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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NALOX-1 PHARMACEUTICALS, LLC,
Petitioner,

v.

OPIANT PHARMACEUTICALS, INC.,
Patent Owner.

Case IPR2019-00694
Patent 9,629,965 B2

Before ERICA A. FRANKLIN, ZHENYU YANG, and MICHAEL A. VALEK, *Administrative Patent Judges*.

VALEK, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
35 U.S.C. § 314(a)

I. INTRODUCTION

Nalox-1 Pharmaceuticals, LLC ("Petitioner"), filed a Petition (Paper 2 ("Pet.")), seeking an *inter partes* review of claims 1–30 of U.S. Patent No. 9,629,965 B2 ("the '965 patent," Ex. 1001). Opiant Pharmaceuticals, Inc. ("Patent Owner"), filed a Preliminary Response. Paper 6 ("Prelim. Resp.").

Under the statute, an *inter partes* review may not be instituted unless the information presented in the petition and the preliminary response shows "there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). On April 24, 2018, the Supreme Court held that a decision under § 314 may not institute review on fewer than all claims challenged in the petition. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1355–56 (2018).

For the reasons provided below, we determine Petitioner has satisfied the threshold requirement set forth in 35 U.S.C. § 314(a). Thus, based on the information presented, and under *SAS*, we institute an *inter partes* review of claims 1–30 of the '965 patent.

II. BACKGROUND

A. Related Proceedings

The '965 patent is one of five patents listed in the Orange Book for intranasal naloxone sold under the brand name NARCAN. Pet. 1; Prelim. Resp. 1. Petitioner concurrently filed IPR2019-00695 and IPR2019-00696, challenging the same claims of the '965 patent with additional prior art.

Petitioner also filed three petitions for *inter partes* review challenging the claims of each of four other patents listed in the Orange Book for NARCAN. Pet. 6. *Inter partes* review of claims 1–29 of U.S. Patent

No. 9,211,253 B2 was instituted in IPR2019-00685. To date, in five other proceedings, the Board has denied institution of *inter partes* review on the petitions challenging these other patents. *See* IPR2019-00686, IPR2019-00687, and IPRs 2019–00691, 692, and 693.

In addition, the parties inform us that the '965 patent is asserted in *Adapt Pharma Operations Ltd. v. Teva Pharmaceuticals USA*, No. 2:16-cv-07721 (D.N.J.) (the "Teva Case") and *Adapt Pharma Operations Ltd. v. Perrigo UK FINCO Limited Partnership*, No. 2:18-cv-15287 (D.N.J.) (the "Perrigo Case"). Pet. 6; Prelim. Resp. 8. Petitioner, however, is not a party to these litigations.

B. Background of Technology and the '965 Patent

Naloxone is an opioid receptor antagonist that was initially approved for use by injection for the reversal of opioid overdose. Ex. 1001, 2:15–17. Naloxone hydrochloride injection prevents or reverses the effects of opioids, "including respiratory depression, sedation and hypotension." Ex. 1044,[1] 1300. The '965 patent explains that "[s]ince the onset of action of naloxone used in opioid overdose cases should be as fast as possible, naloxone is thus far mainly administered intravenously or intramuscularly by emergency health care personnel." Ex. 1001, 6:17–20.

According to the '965 patent, administering naloxone via injection requires trained medical personnel and imposes the risk of exposure to blood borne pathogens through needle-stick injury. *Id.* at 6:26–38. The '965 patent discloses that "it ha[d] been suggested that in view of the

[1] Physicians' Desk Reference 2003, entry for NARCAN (Naloxone Hydrochloride Injection, USP).

growing opioid overdose crisis in the US, naloxone should be made available over-the-counter (OTC), which would require a device, such as a nasal spray device, that untrained consumers are able to use safely." *Id.* at 6:45–49.

The '965 patent acknowledges that nasal administration of naloxone was known and, in fact, had been used by numerous medical services and health departments. *See generally id.* at 2:32–6:54. It points out, however, although some studies "reported that the nasal administration of naloxone is as effective as the intravenous route in opiate addicts," others "reported that naloxone administered intranasally displays a relative bioavailability of 4% only and concluded that the IN [intranasal] absorption is rapid but does not maintain measurable concentrations for more than an hour." *Id.* at 2:50–58. The '253 patent states:

> Thus, there remains a need for durable, easy-to-use, needleless devices with storage-stable formulations, that can enable untrained individuals to quickly deliver a therapeutically effective dose of a rapid-acting opioid antagonist to an opioid overdose patient. The therapeutically effective dose should be sufficient to obviate the need for the untrained individual to administer either a second dose of opioid antagonist or an alternative medical intervention to the patient, and to stabilize the patient until professional medical care becomes available.

Id. at 6:55–64.

The '965 patent purports to meet this need by providing devices adapted for nasal delivery of "a therapeutically effective amount of an opioid antagonist selected from naloxone and pharmaceutically acceptable salts thereof, wherein the device is pre-primed, and wherein the therapeutically effective amount, is equivalent to about 2 mg to about 12 mg of naloxone hydrochloride." *Id.* at 6:55–7:5.

C. Illustrative Claims

Claims 1 and 20 are independent and reproduced below.

> 1. A pharmaceutical formulation for intranasal administration comprising, in an aqueous solution of not more than about 140 µL:
>
> about 4 mg naloxone hydrochloride;
> about 0.74 mg NaCl;
> about 0.01 mg benzalkonium chloride;
> about 0.2 mg disodium edetate; and
> an amount of hydrochloric acid sufficient to achieve a pH of 3.5–5.5.
>
> 20. A single-use, pre-primed device adapted for nasal delivery of a pharmaceutical composition to a patient by one actuation of said device into one nostril of said patient, having a single reservoir comprising a pharmaceutical composition which comprises per 100 µL of aqueous solution:
>
> about 4 mg naloxone hydrochloride or a hydrate thereof;
> between about 0.2 mg and about 1.2 mg of an isotonicity agent;
> between about 0.005 mg and about 0.015 mg of a preservative;
> between about 0.1 mg and about 0.5 mg of a stabilizing agent; and
> an amount of acid sufficient to achieve a pH of 3.5–5.5.

Among other differences, claim 1 differs from claim 20 in that it requires the presence of both benzalkonium chloride (BAC) and disodium edetate (EDTA) in the claimed pharmaceutical formulation, whereas claim 20 recites a "preservative" and "stabilizing agent" generally. Dependent claims 21 and 22 further specify that the preservative in claim 20 is BAC and that the stabilizing agent is EDTA. Dependent claims 23–30, however, depend directly from claim 20 and do not recite such limitations. Therefore, claims

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